Hearing on

Patient Safety and Quality Initiatives

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Testimony by

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I am Dr. Dennis O'Leary, President of the Joint Commission on Accreditation of Healthcare Organizations. I appreciate the opportunity to testify on new patient safety and quality initiatives that are currently underway in this country and, in some instances, around the world.

Founded in 1951, the Joint Commission is a private sector, not-for-profit entity dedicated to improving the safety and quality of health care provided to the public. Our member organizations are the American College of Surgeons; the American Medical Association; the American Hospital Association; the American College of Physicians; and the American Dental Association. In addition to these organizations, the 29-member Board of Commissioners includes representation from the field of nursing as well as public members whose expertise spans such diverse areas as ethics, public policy, insurance, and academia.

The Joint Commission currently accredits over 15,000 organizations in the United States. These include hospitals (both general acute care and specialty), critical access hospitals, laboratories, health care networks (including integrated delivery systems, HMOs and PPOs), ambulatory care, office-based surgery, assisted living, behavioral health care, home care, hospice, and long term care organizations. About one-third of accredited organizations are hospitals, comprising the 80% of hospitals that contain 96% of U.S. hospital beds.

Accreditation is voluntary for all types of accredited organizations. However, both federal and state government regulatory bodies recognize many of the Joint Commission's accreditation programs and rely upon its accreditation findings and decisions for Medicare and licensure purposes. Furthermore, the Joint Commission standards are widely utilized by private sector organizations even where accreditation is not the objective. The Joint Commission also has a large international presence working with major leadership organizations such as the World Health Organization and the World Bank; accrediting individual hospitals in multiple countries; and providing consultation to foreign governments that are seeking to create similar accrediting bodies.

This country has been engaged in a highly visible national dialogue on patient safety for over five years. For an even longer time, the Joint Commission has been working diligently on a number of fronts both to raise professional and public awareness of safety issues and to identify and promulgate a range of workable and necessary solutions. We believe that some notable progress has been made, and the Joint Commission's successful efforts in this regard have been recognized in recent articles by Robert Wachter in *Health Affairs* and by Lucian Leape and Don Berwick in the *Journal of the American Medical Association.* In point of fact, there has been a remarkable change in how leaders in health care organizations talk and think about patient safety issues and how they approach medical errors when they occur. Moreover, there is broad support across the health care industry and among policy-makers for creation of blame-free environments that foster increased reporting of patient safety events. Nonetheless, we have a long way to go to reach our shared goals. This is because the root causes of medical errors and quality problems are numerous, complex, and hard-wired into the way we deliver health care. We therefore need a multifaceted, multi-stakeholder approach to ensuring that high quality, safe care is provided on a consistent and predictable basis in this country.

Today, I would like to highlight some of the initiatives in which the Joint Commission is engaged in its continuing efforts to improve care, and to also suggest some areas that merit further exploration.

The Joint Commission's efforts to improve patient safety are based upon a fundamental recognition of the need for provider organizations and practitioners to adopt a "systems approach" to managing risk and keeping inevitable human error from reaching patients. The systems approach idea is borrowed from engineering and quality control principles which have been successfully applied in manufacturing and other industries to mitigate the effects of human error. The growing awareness of practices used in other high risk endeavors (e.g., in the nuclear power and airline industries) to create safety, makes clear that a name, blame, and shame approach to safety will fail, and that the end goal must be the design of safe systems—systems that are designed to anticipate human error and prevent the occurrence of adverse events.

This approach to safety—"systems thinking"—requires tools such as retrospective root cause(s) analysis when adverse events occur and prospective failure mode and effects analyses to identify and eliminate risks in identified vulnerable processes before actual adverse events can occur. This approach also requires a learning environment in which errors and preventable harms are identified (rather than hidden) so that they can become learning experiences for the organization.

Also required is an organizational environment that is safety-focused; that is, one in which safety is always top of one's mind; in which reporting of errors and unsafe conditions is rewarded, not punished; in which apology, honesty, and transparency characterize the relationship with patients who have been harmed through error; and in which there is constant vigilance for emerging risks. This type of organization environment—often called a "culture of safety"—only develops when the organization's administrative and clinical leaders collaboratively and intentionally create it.

Tools for Change

With this framework in mind, the Joint Commission has created a substantial portfolio of initiatives, practical tools, and solutions for patient safety over the past decade. Taken together, they constitute a roadmap for organizations that are seeking ways to improve their performance and enhance patient safety. Concepts and tools are critical ingredients for any type of sea change. If we are to truly achieve improvements in patient safety, we must give health care organization leaders, clinicians and patients the information, tools and potential solution they need to effect such changes.

The patient safety initiatives that I would like to highlight today are: 1) our new International Center for Patient Safety, 2) new accreditation standards, 3) the Sentinel Event Policy and *Alerts*, 4) the National Patient Safety Goals and Universal Protocol, 5) the *Speak-Up* Campaign, 6) the Patient Safety Event Taxonomy, 7) the 100 Thousand Lives Campaign, and 8) selected recommendations from our initiative to link potential improvements in the medical liability system to the prevention of patient injury.

International Center for Patient Safety (ICPS)

In March of this year, the Joint Commission launched a new International Center for Patient Safety (ICPS). The Center will initially focus on the identification, gathering, analysis, and dissemination of patient safety solutions, both in this country and abroad, and upon the creation of organization cultures of safety which embrace continuous attention to safety-focused, systems improvement efforts. These are seen as the most significant near-term opportunities for achieving major advancements in patient safety. The center will also serve as a focal point for research and related efforts to develop additional patient safety-related solutions. The center will obtain input, feedback and guidance through an international steering committee of patient safety experts, five global regional advisory councils, and strategic domestic and international partnerships with other patient safety leadership organizations.

The Patient Safety Center recently launched a new Web site which will serve as a central repository of resources and information related to all aspects of patient safety. Its content is relevant to patients, provider organizations, purchasers, physicians, nurses, and other practitioners. Health care organizations and health professionals will, for example, be able to use the Center's Web site to find information on the most frequent types of identified sentinel events and their root causes and resources for understanding and meeting the Joint Commission's National Patient Safety Goals. Patients and their families, as well as purchasers, will be able to use the Center's Web site to obtain quality-related performance information on health care organizations, become familiar with public education campaigns on patient safety such as the Joint Commission's *Speak Up Campaign,* and become knowledgeable about public policy issues that impact patient safety. Online discussion groups will provide an interactive forum for international dialogue on critical patient safety issues and topics.

The Center's Web site will also become the focus of the Center's efforts to create a worldwide collaborative network of patient safety leadership organizations. The international context is particularly significant, because patient safety is a universal problem. In fact, the World Health Organization launched its own World Alliance for Patient Safety in October 2004, and the Joint Commission and Joint Commission International are now involved in several of the Alliance's

major initiatives. These include the lead role for creation of an International Patient Safety Events Taxonomy and designation as the WHO International Collaborating Center for Patient Safety Solutions, to coordinate the work of the Alliance's Solutions Initiative. A WHO collaborating center is a national institution designated by the Director-General of the World Health Organization to participate in an international collaborative network that carries out activities in support of WHO's mandate to promote international health.

The World Alliance for Patient Safety has been charged to conduct six initiatives over the next two years:

- Global Patient Safety Challenge—to focus on the reduction of health care- associated infections through the promotion of hand washing and other preventive efforts.
- Patients for Patient Safety—to identify and create a network of patient and consumer groups interested in identifying and promoting constructive patient safety solutions.
- International Patient Safety Events Taxonomy—to utilize the Joint Commission's Patient Safety Events Taxonomy to create a high level international umbrella taxonomy that accommodates taxonomies already in existence in other countries.
- Research for Patient Safety—to undertake prevalence studies of adverse events in selected developed and developing countries and to pursue other patient safety research initiatives.
- Solutions for Patient Safety—to identify, gather, evaluate and disseminate patient safety solutions that are tailored to the needs of developing and developed countries.
- Reporting for Learning—to identify best practice guidelines for reporting systems that facilitate learning from adverse events and analyses of their underlying causes.

The Joint Commission's International Center for Patient Safety will shortly convene the principal patient safety leadership organizations in the United States to explore opportunities to collaborate in coordinating the identification and dissemination of patient safety solutions and in pursuing other opportunities to improve patient safety. Those organizations that have agreed to participate are the Agency for Healthcare Research and Quality, United States Pharmacopeia, VA National Center for Patient Safety, ECRI, Institute for Healthcare Improvement, Institute for Safe

Medication Practices, the Leapfrog Group, the National Patient Safety Foundation and the National Quality Forum.

Patient Safety Related Standards

One of the key elements in the Joint Commission's commitment to patient safety is the development, updating, and deployment of state-of-the-art patient safety standards. Over half of Joint Commission standards are directly related to safety — addressing such issues as medication use, infection control, surgery and anesthesia, blood transfusion, restraint and seclusion, staffing and staff competence, fire safety, medical equipment maintenance, emergency management, and security, among other areas.

In recent years, new and revised standards now require the internal definition, reporting and in-depth analysis of serious adverse events; internal systems improvements based on these analyses; the implementation of comprehensive virtual patient safety programs that actively engage organization leaders; the prevention of accidental harm through the prospective analysis and redesign of vulnerable patient systems (e.g. the ordering, preparation and dispensing of medications); and transparency in the communication of outcomes of care—whether good or bad – from the organization (usually through the responsible physician) to the patient. The Joint Commission has also taken steps to ratchet up the performance expectations respecting medication management and infection control and has introduced patient flow standards to mitigate the impacts of emergency department overcrowding on patient safety. Under development are major standards revisions that will substantially increase the stringency of current processes for credentialing physicians and licensed, independent practitioners and assessing their competency in the performance of various clinical procedures. These enhanced expectations anticipate increasing greater use of performance data as part of both the privileging and performance monitoring process.

Sentinel Event Policy

In 1995, the Joint Commission developed and implemented a Sentinel Event Policy that encourages the voluntary reporting of serious adverse events and requires the performance of root cause analyses that meet pre-determined criteria for thoroughness and credibility. Soon thereafter, the Joint Commission began to characterize and organize the reported events and their underlying causes for all identified occurrences (whether self-reported or otherwise), into a learning database. The resulting Sentinel Event Database is now this country's most complete record of the full spectrum of serious medical errors and their underlying causes. This database, combined with knowledge gained from working with health care organizations on a daily basis to address their patient safety problems, has given us a deep understanding of the interplay and complexity of factors that contribute to serious adverse events. It has also helped us craft solutions to some common safety issues. The solutions represent a range of actions - both low and high cost – that can be taken at various levels of the health care system and in which different stakeholder groups can participate.

The Sentinel Event Policy and its resultant database have proven their value. However, we would have many more reports and a more robust understanding of root causes of error if there were federal protection for reporting adverse events and near-misses. This Subcommittee has previously shown strong leadership in this area, and we hope it will continue to work toward passage of such safe harbor legislation this year.

Sentinel Event Alerts

For the past seven years, patient safety solutions from the Sentinel Event Database have been disseminated in the periodic publication, *Sentinel Event Alert*. Since its creation, over 30 issues of *Sentinel Event Alert* have raised awareness in the health care community and the federal government about the occurrences of adverse events and the ways in which these events can be prevented. By distributing *Sentinel Event Alert*, the Joint Commission encourages organizations to implement the suggestions found with the publication to prevent errors and enhance patient safety. The most recent topics covered in *Sentinel Event Alerts* have been patient controlled analgesia by proxy and anesthesia awareness.

National Patient Safety Goals

Based upon the data from the Sentinel Event Database and other patient safety databases, and the advice of a national panel of patient safety experts, the Joint Commission now annually establishes and issues a set of National Patient Safety Goals and associated Requirements. The purpose of the Joint Commission's National Patient Safety Goals is to focus attention on obvious, relatively straight-forward, inexpensive patient safety solutions that all accredited organizations are expected to adopt. The goal-related requirements are specifically surveyed during the onsite accreditation survey, and the organization's performance with respect to each National Patient Safety Goal is reported in an organization-specific Quality Report on the Joint Commission's public website (www.qualitycheck.org). This public disclosure is not of errors or adverse events, but, rather, of whether the organization is performing the specific safe practices described in the Requirements.

Last month, the Joint Commission Board affirmed its required "do not use" list of abbreviations. The list was originally created in 2004 by the Joint Commission as part of a National Patient Safety Goal which mandates identification of a list of abbreviations, acronyms and symbols that are not to be used throughout the organization. Participants at a 2004 Summit convened to address this issue supported the "do not use" list. During the ensuing four-week comment period, the Joint Commission received 5,227 responses that included 15,485 comments. More than 80 percent of the respondents supported maintenance of the "do not use" abbreviation list.

Universal Protocol

In 2003, the Joint Commission's Board of Commissioners approved a separate Universal Protocol for Preventing Wrong Site, Wrong Procedure and Wrong Person Surgery as a supplement to the National Patient Safety Goals. The Universal Protocol was created to staunch the continuing occurrence of a specific type of adverse type that should simply never occur. The Universal Protocol became effective July 1, 2004 for all accredited hospitals, ambulatory care and office-based surgery facilities. The Universal Protocol drew upon, and expanded and integrated, a series of previous requirements under the Joint Commission's 2003 and 2004 National Patient Safety Goals and is applicable to all operative and other invasive procedures.

The principal components of the Universal Protocol include: 1) the pre-operative verification process; 2) marking of the operative site; and 3) taking a 'time out' immediately before starting the procedure. The protocol has been endorsed by nearly 50 professional associations and societies.

Speak-Up Campaign

Several years ago, the Joint Commission, together with the Centers for Medicare and Medicaid Services, launched a national program to urge patients to take an active role in preventing adverse events in health care by becoming involved and informed participants on the health care team. The program utilizes various media to reach patients and consumers, including incorporation into selected purchaser employee benefits strategies, and has been embraced by a number of provider organizations and practitioners. The original *Speak Up* initiative was subsequently expanded to *Help Prevent Errors in Your Care for Surgical Patients*. This campaign provided tips to help patients prepare for surgery and assure their involvement in making certain that the correct procedure is performed at the correct body site. The two campaigns launched in 2004 included *Preparing to be a Living Organ Donor* which urges individuals to think through the risks and realities of becoming a living organ donor, and *Three Things You Can Do To Prevent Infection* which highlights a series of easy to steps anyone can take to avoid contagious respiratory diseases like the common cold, strep throat, and influenza. This year, the Joint Commission launched *Things You Can Do To Prevent Medication Mistakes*. This provides important tips for preventing medication mistakes and outlines key questions that the patient may want to pose to the doctor, pharmacist, nurse or other caregiver. Additional patient safety topics —such as discharge planning and pain management — stroke will be addressed in the future.

Standardized Patient Safety Events Taxonomy

It is no small irony that the progressively expanding national discussions on patient safety over the past several years are not based on a common language. For example, there are no agreed upon definitions of "medical error" or "adverse event," making it extremely difficult, if not impossible, to aggregate safety data across various types of reporting programs. This critical missing element has hindered our collective ability to collect patient safety data in a consistent

fashion, analyze process failures, mine data (e.g., trends, pattern analysis), and disseminate new knowledge about patient safety. In response to this challenge, the Joint Commission has created the framework for a comprehensive Patient Safety Event Taxonomy. This taxonomy is currently in the final stages of the National Quality Forum's consensus development process. Having a standardized taxonomy will facilitate the management of patient safety data and the development of patient safety reporting systems. It should eventually have broad potential utility for consumers, provider organizations, health care practitioners, purchasers, researchers and other audiences.

As noted previously, this taxonomy is being used as the starting point for a WHO-led project to create an international Patient Safety Events Taxonomy. The development of a common international framework for classifying, measuring, and reporting adverse events and near misses is one of the principal technical components of the WHO's global strategy to improve health care delivery systems, product safety (devices, drugs, biologics, and vaccines) and the safety of services (medical decision-making, diagnosis, and laboratory analysis). The intent is to create a scalable, portable framework that can be used to classify patient safety incidents reported through different systems in different countries with varying levels of technology.

100,000 Lives Campaign

Much of what the Joint Commission does and achieves is realized through partnerships with other health care leadership organizations. This past winter, the Joint Commission announced that it was joining with the Centers for Medicare and Medicaid Services to partner with the Institute for Healthcare Improvement in the national campaign to save 100,000 lives by June 2006. The campaign aims to enlist thousands of hospitals across the country in a commitment to implement changes to prevent avoidable deaths. The 100,000 lives campaign is viewed by the growing number of partners and participants as an outstanding opportunity to realize some of the Institute of Medicine's major goals through a concentrated effort. Hospitals that choose to participate in the campaign will specifically commit to implement one or more of the following six quality improvement changes:

* Deploy Rapid Response Teams at the first sign of patient decline

* Deliver reliable, evidence-based care for Acute Myocardial Infarction to prevent deaths from heart attack
* Prevent adverse drug events by implementing medication reconciliation
* Prevent central line infections by implementing a series of interdependent, scientifically grounded steps called the "Central Line Bundle"
* Prevent surgical site infections by reliably delivering the correct perioperative antibiotics at the proper time
* Prevent ventilator-associated pneumonia by implementing a series of interdependent, scientifically grounded steps called the "Ventilator Bundle"

Strategies for Improving the Medical Liability System and Preventing Patient Injury

Through its Public Policy Initiatives, the Joint Commission periodically tackles tough patient safety and health care quality issues that would benefit from an independent voice. This year, the Joint Commission released a public policy report called "Strategies for Improving the Medical Liability System and Preventing Patient Injury." The initiative was spurred by the chilling effect that the current system has on identifying and reporting adverse events in health care; by large jury awards; the exorbitantly high cost of defensive medicine; and by the fundamental lack of fairness of the current system in compensating injured patients. The Joint Commission wanted to broaden the debate over liability reform to encompass the patient safety issues that fuel litigation at the front end.

To address this issue, the Joint Commission convened a roundtable of experts in law, medicine, health care policy and related research, as well as patient safety advocates to frame the issues and create recommendations for action. The basic finding of the Roundtable was that there is a fundamental dissonance between the medical liability system and patient safety. Patient safety depends upon the transparency of information on which to base improvement, while medical liability drives information underground and out of reach to those who could most benefit from it. Of the more than a dozen recommendations from the recently issued report, several are relevant to this hearing today.

1) Encourage appropriate adherence to clinical guidelines and performance recognitions.
Adherence to clinical guidelines has long been touted as an effective way in which to improve quality, reduce variation in care, and improve financial performance. However, there is also a significant relationship between medical liability and clinical guidelines. A new study has shown that adherence to guidelines can have a substantial role in reducing legal risk. One way to promote greater use of clinical guidelines and consensus approaches to patient safety solutions is to pursue strategies that provide incentives to focus on improvements in patient safety and health care quality.

Pay for performance programs, for example, hold great promise for transforming the health care system to achieve the Institute of Medicine's six aims (safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity.) Indeed, only small, symbolic rewards may be needed to achieve desired behavior changes. Also on this point, pay for performance opens a larger opportunity to reform. Reimbursement systems today usually fail to recognize, let alone compensate for necessary investments by provider organizations and practitioners in patient safety.

2) Encourage communication between practitioners and patients when an adverse event occurs.
One of the basic principles of patient safety is to communicate with and listen to patients. Several elements are fundamental to any disclosure effort when an adverse event occurs. These include a prompt explanation of what is understood about what happened and its probable effects; assurance that an analysis will take place to understand what went wrong; follow-up based on the analysis to make it unlikely that such an event will happen again; and an apology. The Joint Commission's accreditation standards require the disclosure of sentinel events and other unanticipated outcomes of care to patients and to their family members when they occur. A recent study nonetheless confirms that half of hospitals are reluctant to comply with this standard for fear of liability suits. But there is growing consensus that this openness has the potential to heal, rather than harm relationships between practitioners and patients.

3) National Practitioner Data Bank

One of the ways through which health care organizations seek to assess competencies of their physicians and other practitioners with clinical privileges is to query available data sources about disciplinary actions or medical liability judgments and settlements. However, such information is impossible to obtain from any one source. We need a centralized repository, or a network of linked sources, to make such information available. The Department of Health and Human Services, through the Health Resources and Services Administration, operates the National Practitioner Data Bank (NPDB) to permit hospitals and licensing boards to track physician performance issues. However, since its inception, the reliability, validity, and completeness of the NPDB's information have been questioned. A 2000 GAO report pointed out the need for reform of the NPDB. We believe that pursuit of these reforms is long overdue. The only reliable alternative is to create an alternative resource to house this information in the private sector.

Concluding Remarks

In conclusion, there remains much work to be done to truly change the culture of our complex health care delivery system to fully embrace patient safety and health care quality. The health care industry is a victim of its rapid success in the explosion of biomedical science, sophisticated technologies, and trained personnel who have highly specialized knowledge. Much progress has been made in improving patient safety since the IOM issued its report, To Err Is Human, but we may actually be falling further behind as new drugs, procedures and technologies are introduced every day. Each of these have inherent safety risks that have not been identified, and they will, for the most part, be introduced into care delivery settings where patient safety and systems thinking ("to keep the error from reaching the patient") are not constantly top of mind. In addition, the absence of electronic information exchange capabilities to provide decision support makes it virtually impossible for practitioners to maintain a current clinical knowledge base.

The knowledge of what to do differently and how to do it exists but we are we are far closer to the beginning of the journey than we are to the end. We as a society must ramp up our efforts if we are to successfully bridge the chasm between the current state of health care and what is truly safe, high quality care.